

EXHIBIT D

Olga Ramm, M.D

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
3 CHARLESTON DIVISION
4 IN RE: ETHICON, INC., Master File No.
 PELVIC REPAIR SYSTEM 2:12-MD-02327
5 PRODUCTS LIABILITY MDL 2327
 LITIGATION, JOSEPH R. GOODWIN
6 U.S. DISTRICT JUDGE

7 _____

8 THIS DOCUMENT RELATES TO:

9 Wave 4 Cases

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15 *GENERAL RE: TVT MATTER*

16 DEPOSITION OF OLGA RAMM, M.D.

17 Oakland, California

18 Friday, March 17, 2017

19 Volume I

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22 REPORTED BY:

23 REBECCA L. ROMANO, RPR, CSR No. 12546

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15 DEPOSITION OF OLGA RAMM, M.D., taken on behalf
16 of the Plaintiff, at Oakland Marriott City Center,
17 1001 Broadway, Conference Room 212, Oakland, California,
18 commencing at 9:34 a.m., Friday, March 17, 2017 before
19 Rebecca L. Romano, Certified Shorthand Reporter
20 No. 12546

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1 A. No, I don't believe that.

2 Q. Doctor, have you reviewed the IFU?

3 A. I have.

4 Q. Which ones?

5 A. I reviewed the 2015, as well as the 2011 IFU.

6 Q. And did you find the 2015 IFU to be
7 sufficient?

8 A. The 2015, is that the one you are asking
9 about?

10 Q. Yes.

11 A. I actually found both of them to be
12 sufficient.

13 Q. Now, did you review any IFUs besides the 2015
14 and 2011?

15 A. About the TVT, specifically?

16 Q. About the TVT, specifically.

17 A. I don't think so.

18 Q. So you didn't review the 2000 IFU; is that
19 correct?

20 A. I may -- I may have reviewed it.

21 MR. SNELL: You are allowed to look through
22 your stuff, if it will help you to refresh your
23 recollection.

24 MS. LIU: And I appreciate if Counsel would
25 not coach the witness.

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1 foundation as well.

2 THE DEPONENT: So when I explant mesh,
3 there's no gross evidence of inflammation around the
4 mesh. There's good tissue incorporation that's seen.
5 You know, that's why it's sometimes difficult to remove
6 mesh.

7 Q. (By Ms. Liu) But you have never actually
8 examined mesh, like an explanted mesh piece, under
9 electron microscope to see whether or not there's
10 evidence of chronic inflammation; is that correct?

11 MR. SNELL: Objection. Asked and answered.

12 THE DEPONENT: I haven't, but I'm not -- I
13 don't believe that an electron microscopy image would
14 even be indicative of inflammation. I think
15 inflammation is something that is better assessed with
16 plain histology.

17 Q. (By Ms. Liu) And, Doctor, you are not a
18 pathologist, are you?

19 A. I am not a pathologist; although, I've worked
20 closely with pathologists.

21 Q. But you have never performed the work of a
22 pathologist?

23 A. I'm not a pathologist.

24 Q. Doctor, we talked a little bit about the IFU
25 earlier, and you had stated that you specifically

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1 remember reviewing the 2015 and the 2011 IFUs, correct?

2 A. Correct.

3 Q. Doctor, have you ever written an IFU?

4 A. I have not written an IFU.

5 Q. Have you ever given input to a medical device
6 company on what needs to be in an IFU?

7 A. I have not.

8 Q. Would you consider yourself to be an expert
9 in drafting IFUs?

10 A. I have used IFUs. I have been the end user,
11 the intended audience of IFUs.

12 Q. But you have never drafted one, correct?

13 A. I have not drafted an IFU, not --

14 Q. Do you know -- sorry. Didn't mean to cut you
15 off.

16 Do you know what the regulations are of what
17 needs to be in an IFU?

18 A. So in preparation for this case, I -- I have
19 reviewed some of the FDA regulations around IFUs.

20 Q. Do you know which regulations they were?

21 A. I don't remember the exact number. There --
22 there are lots of regulations, but they were specific
23 for medical devices whose use would be limited to train
24 physicians --

25 Q. Now --

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1 complications about their product; is that correct?

2 MR. SNELL: Objection. Asked and answered.

3 THE DEPONENT: I -- in this specific case, we
4 are so far into the litigation that I imagine Ethicon
5 has a pretty good sense of what the complaints are and
6 has painstakingly reviewed them. But if we are talking
7 in general about a surgery procedure that involves --
8 you know, whether an implant or a device or whatnot,
9 no. I would not expect that the manufacturer have
10 their finger on the pulse of all of the complications
11 or latest developments. I think that is for the
12 practicing community that actually utilizes that.

13 Q. (By Ms. Liu) And do you believe that the
14 manufacturer who is selling the product should be
15 keeping up with all the -- all the complications about
16 their product?

17 A. I don't think -- I think they shouldn't be
18 ignoring those complications, certainly.

19 Q. Doctor, do you believe that the TVT mesh has
20 a potential to degrade?

21 A. I don't believe that, no.

22 Q. Doctor, have -- you stated -- strike that.

23 Doctor, you stated earlier that you have not
24 looked at any explanted mesh under electron microscope;
25 is that correct?

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1 is also corroborated by all of the clinical data that
2 shows sustained efficacy in the long term in terms of
3 stress incontinence cure for women who have had the TVT
4 implant.

5 Q. And, Doctor, your experience is clinical
6 experience, correct?

7 A. Well, my experience is my own clinical
8 experience, but it is also the -- the added experience,
9 so to speak. We are all privileged to have the added
10 experience of the entire academic community that
11 publishes studies and also that then creates
12 meta-analyses to pool the data.

13 Q. And, Doctor, have you designed any mesh
14 products before?

15 A. I haven't designed mesh products, no.

16 Q. Do you know what goes into the design of a
17 mesh product?

18 A. Well, it depends on what you mean by
19 "design," but I have a rough understanding of what went
20 into the design of the TVT, for example, based on the
21 articles that I reviewed by Petrus and by Olmsted.

22 Q. And, Doctor, you mentioned Olmsted.

23 Are you aware that Olmsted was compensated
24 based on positive results?

25 MR. SNELL: Object. Lacks foundation. Also

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1 that look specifically at dyspareunia after stress
2 incontinence surgery, not the TVT, and after pelvic
3 reconstructive surgery, in general.

4 Q. (By Ms. Liu) And, Doctor, I know that I
5 skipped around a little bit. I want to circle back
6 around to your experience.

7 Your experience, in generating your report,
8 has been clinical experience, correct?

9 MR. SNELL: Object. Misstates.

10 THE DEPONENT: So, again, my experience is a
11 combination of my own clinical experience, the clinical
12 experience of my colleagues, my training, my review of
13 the literature; and specific to the generation of the
14 report, also my review of company documents.

15 Q. (By Ms. Liu) And, Doctor, you stated before
16 that you have not designed a medical device.

17 Have you designed any type of polymer before?

18 A. I have not designed a polymer.

19 Q. You wouldn't purport yourself to be a polymer
20 expert, would you?

21 MR. SNELL: Objection.

22 THE DEPONENT: I believe that I am an expert
23 in the polypropylene polymer based on my clinical use
24 of it, based on my review of the literature surrounding
25 its design and applications.

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1 Q. (By Ms. Liu) Are you a materials engineer?

2 A. I don't have that degree, no.

3 Q. Have you designed any materials before?

4 A. I haven't personally designed materials.

5 Q. Have you provided any input to a medical
6 device company on how to design a sling, for example?

7 A. Informally, I have given feedback about
8 the -- the clinical applications of mesh.

9 Q. And have you given any opinions to a medical
10 device company as to the weight of the mesh -- of what
11 the mesh should be?

12 A. I haven't personally done that, no.

13 Q. Have you given a medical device company what
14 you believe the pore size -- the optimum pore size of
15 the mesh should be?

16 A. So, again, not personally, because those
17 questions were actually answered before I was
18 mid-career, right? I'm fortunate to practice in a time
19 where those questions have been answered.

20 Q. So -- but to answer my question, you have
21 never given, then, any opinion as to how the TVT or any
22 type of sling should be designed, correct?

23 A. Correct.

24 MR. SNELL: Object to form.

25 MS. LIU: Off the record.